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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/773,480 | 02/06/2004 | Michel Dib | FRAV2003/0003 US NP | 7069 |
| 5487 | 7590 | 07/31/2007 | EXAMINER | |
| ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807 | | | KIM, JENNIFER M | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1617 | | |
| | | NOTIFICATION DATE | DELIVERY MODE | |
| | | 07/31/2007 | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com
andrea.ryan@sanofi-aventis.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/773,480 | DIB ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Kim | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 June 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/16/2004.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group I, claims 1-7, drawn to a method for the treatment of sleep disorders is acknowledged. The traversal is on the ground(s) that there is no burden on the Examiner to search all of the groups together because that the nine (9) methods of treatment comprise the administration of the same active pharmaceutical agent to a patient for the treatment of a central nervous system (CNS) disorder and the therapeutic target and those nine inventions are in the same search classification. This is not found persuasive because the claims are drawn to various number of disorders that are not related due to their divergent subject matter. Each of the medical disorders to be treated have different known treatment exhibiting different symptoms, for example treatment of insomnia (having symptoms of difficulty sleeping) is completely different than treatment of extrapyramidal event induced by an antipsychotic (having symptoms of tremor). Therefore, serious burden would be placed on the Examiner to search and consider all of the unrelated medical disorder involving different symptoms, different biological pathways, different mechanisms, different known/unknown treatments and different etiologies if the restriction requirement is not made. Therefore, the restriction requirement made on the previous Office Action is deemed proper and made FINAL.

Accordingly, claims 1-7 are being examined and claims 8-20 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al. (1973).

It is noted that claims are drawn to a method of treating **a patient** for sleep disorders comprising administering to said patient 2-cyano-10-(2-methyl-3-(methylamino)propyl)phenothiazine (also known as cyamemazine).

Singer et al. teach 2-cyano-10-(2-methyl-3-(methylamino)propyl)phenothiazine (also known as cyamemazine) is mainly indicated for the treatment of insomnia. (abstract). (see claims 1-3) Singer et al. also teach 2-cyano-10-(2-methyl-3-(methylamino)propyl)phenothiazine (also known as cyamemazine) was used as a sedative narcoleptic agent in 20 males and 20 female psychiatric inpatients. (see claims 1-5).

It is noted that the patient population to be treated is not defined by the instant claims because claims are drawn to treating sleep disorders in any patient.

Therefore, this teaching anticipated the claimed subject matter of treating "a patient" administering the same active agent of cyamemazine involving the same method steps. Accordingly, upon utilization of the same active agent to the same population "a patient" would inherently have the same effect.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (1973).

Singer et al. teach 2-cyano-10-(2-methyl-3-(methylamino)propyl)phenothiazine (also known as cyamemazine) is mainly indicated for the treatment of insomnia, psychomotor agitation, and delirium. (abstract). Singer et al. also teach that the cyamemazine is used as a sedative narcoleptic in the patient with psychiatric condition. (abstract).

Singer et al. do not teach the specific amounts set forth in claim 6, the treatment of insomnia related to another mental disorder set forth in claim 4 and route of administration set forth in claim 7.

It would have been obvious to one of ordinary skill in the art to employ cyamemazine for the treatment of insomnia related to another mental disorder because Singer et al. teach that cyamemazine is mainly indicated for insomnia and delirium (mental disorder). Further, Singer et al. illustrate the administration of cyamemazine to psychiatric patients to achieve a sedative narcoleptic effect. One of ordinary skill in the art would have been motivated to employ cyamemazine to insomnia related to other disorders, particularly a disorder relating to mental status in order to achieve its main indicated effective treatment of both insomnia and mental disorder. There is a

reasonable expectation of successfully treating insomnia related to another mental disorder because cyamemazine is useful for both disorders of insomnia and mental disorder and because Singer et al. demonstrates the actual administration of cyamemazine to psychiatric patients. The amounts of active agent to be employ set forth in claim 6 and the route of administration are all deemed obvious because Singer teaches the main indication of cyamemazine of treating insomnia and mental disorder, it is within the one of ordinary skill in the art to optimize the dosage and route of administration to be employ according to factors involving severity of condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition and patients preference.

Claim 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (1973) in view of Tilkian (1978).

This rejection is made based in the assumption that the patient population being treated in claim 5 is **suffering** from obstructive sleep apnea.

Singer et al. teach 2-cyano-10-(2-methyl-3-(methylamino)propyl)phenothiazine (also known as cyamemazine) is mainly indicated for the treatment of insomnia. (abstract).

Singer et al. do not teach the treatment of obstructive sleep apnea.

Tilkian teaches insomnia is a symptom of obstructive sleep apnea. (abstract).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ cyamemazine for the treatment of obstructive sleep apnea patients having insomnia because cyamemazine is effective in treatment of insomnia as taught by Singer et al. and because insomnia is a symptom of obstructive sleep apnea. One would have been motivated to make such a modification in order to successfully treat obstructive sleep apnea by treating the symptom of obstructive sleep apnea, insomnia that is effectively treatable with cyamemazine in view of Singer et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

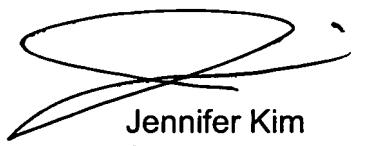
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
July 22, 2007